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Summary of Safety and Effectiveness

Date: September 26, 2011

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
SMR Resurfacing Shoulder System	HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; Class II per 21 CFR 888.3690
	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II per 21 CFR 888.3660

Description:

The SMR Resurfacing Shoulder System consists of a humeral head, a humeral stem and an optional glenoid. The SMR Resurfacing Shoulder Prosthesis is intended for partial or total shoulder replacement. The heads and the stems are intended for uncemented use only. The glenoid components, used in total shoulder replacement, are intended for cemented use only. The glenoid components were previously cleared for use in the SMR Shoulder System in K100858.

Two versions of the SMR Resurfacing humeral heads are available: standard and CTA. Both versions have a spherical polished articulating surface with a plasma spray titanium coated inner surface. In the inner part of the head a male taper allows coupling with the humeral stem. The CTA version of the head is characterized by an extended articulating surface to keep the implant surface in contact with the acromion in patients with irreparable rotator cuff tear arthropathy. Eight sizes are available for the SMR Resurfacing standard heads (from 40 to 54mm diameter, increasing 2mm for each greater size); seven sizes are available for the SMR Resurfacing CTA heads (from 42 to 54mm diameter, increasing 2mm for each greater size). Heads are made from CoCrMo (ASTM F1537); the inner surface is plasma spray titanium coated (ASTM F1580).

The SMR Resurfacing humeral stem is characterized by a female taper for coupling with the resurfacing head. The external geometry of the stem has two taper angles and a fluted cross-section. The stem is externally sand-blasted. Two sizes of stems are available: 11

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mm diameter (length 32 mm) and 13 mm diameter (length 36 mm). Stems are made from Ti6Al4V (ISO 5832-3 – ASTM F1472).
The glenoid components are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE ISO 5834-2, ASTM F648). The articulating surface has a radius of curvature greater than the corresponding humeral head, which allows translation in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has a single central peg which is inserted in the hole drilled in the glenoid cavity during surgery. The peg surface has three grooves to provide enhanced cement fixation.

Intended Use/Indications:

The SMR Resurfacing Shoulder Prosthesis system is indicated for partial or total primary shoulder replacement in patients where the humeral head and neck have sufficient bone stock to support the prosthesis.

The Standard Resurfacing heads are indicated for partial or total shoulder replacement when the rotator cuff is intact or reconstructable. Specific indications include:
- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Post-traumatic osteoarthritis;
- Rheumatoid arthritis.

The CTA Resurfacing Heads are indicated for partial shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:
- Rotator cuff tear arthropathy.

The humeral heads and stems are intended for uncemented use only. The glenoid components, used in total shoulder replacement, are intended for cemented use only.

Predicate Devices:

- Copeland MB Resurfacing Humeral Heads (Biomet, K010657);
- Copeland EAS Humeral Resurfacing Heads (Biomet, K051843);
- Global CAP Resurfacing Replacement Shoulder(DePuy Orthopaedics, K031971);
- Global CAP CTA Resurfacing Shoulder (DePuy Orthopaedics, K080990);
- Bio-Modular shoulder system (Biomet, K992119);
- DePuy Global Shoulder Glenoid (DePuy K981487).

Comparable Features to Predicate Devices:

The intended use and indications for the Limacorporate SMR Resurfacing Shoulder System are similar to those of the referenced predicate devices. Like the predicate

devices, the humeral head and stem components of the SMR Resurfacing Shoulder System are intended for uncemented use only. Like the Copeland Resurfacing Heads, the SMR Resurfacing Shoulder System can be used in Partial or Total Shoulder Arthroplasty. The SMR and predicate glenoids are all intended for cemented use only.

The heads of the SMR Resurfacing Shoulder Prosthesis are available in two versions (standard head and CTA head) similar to the designs offered in the predicate devices. The SMR Resurfacing Shoulder Prosthesis has a modular design (head and stem coupled by means of a Morse taper) while the predicates are monolithic. Apart from this difference, the design of the SMR Resurfacing Shoulder Prosthesis is similar to the predicate devices with a spherical polished articulating surface (extended for the CTA version) and a coated inner surface. The SMR glenoids feature a single central peg and cement pockets to achieve fixation while predicate glenoids are available with multiple pegs or a keeled design.

The material used for the heads of the SMR Resurfacing Shoulder Prosthesis (CoCrMo) is identical to that used for the predicate devices, while the humeral stems of the SMR Resurfacing system are made from Ti6Al4V. The SMR and the Biomet Bio-modular all-poly glenoids are made from UHMWPE while DePuy Global Shoulder Glenoids are made from crosslinked polyethylene.
The diameters of the standard heads of the SMR Resurfacing Shoulder Prosthesis are comparable to those of the Global CAP Resurfacing Replacement Shoulder. The diameters of the CTA heads of the SMR Resurfacing Shoulder Prosthesis are comparable to those of the Copeland EAS Humeral Resurfacing Heads. The heights of the heads and the lengths of the stems of the SMR Resurfacing Shoulder Prosthesis are comparable to those of the DePuy predicate devices.

All systems utilize single use devices which are provided sterile. Shelf life for the components of the SMR Resurfacing System is 5 years.

Non-Clinical Testing:

The SMR Resurfacing Shoulder System has undergone static disassembly and fatigue testing with post-test evaluation of connection strength and examination for corrosion to verify the strength of the taper assembly between the stems and the heads. The SMR Resurfacing stems have undergone torsional tests to test primary stability. The testing results demonstrated the device's ability to perform under expected clinical conditions.
Testing of the glenoid components according to ASTM F1829 and ASTM F2028 was submitted in K100858. No additional glenoid testing was performed for this application because the previous testing with SMR total shoulder humeral heads also supports glenoid performance with the SMR Resurfacing system.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Resurfacing Shoulder System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K112900
Trade/Device Name: SMR Resurfacing Shoulder Prosthesis
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD, KWS
Dated: May 4, 2012
Received: May 8, 2012

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

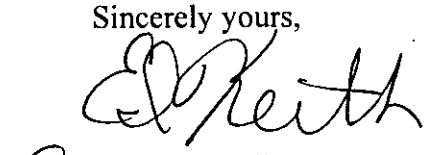
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ K112900

Device Name: SMR Resurfacing Shoulder System

Indications for Use:

SMR Resurfacing Shoulder System
Indications for Use

The SMR Resurfacing Shoulder Prosthesis system is indicated for partial or total primary shoulder replacement in patients where the humeral head and neck have sufficient bone stock to support the prosthesis.

The Standard Resurfacing heads are indicated for partial or total shoulder replacement when the rotator cuff is intact or reconstructable. Specific indications include:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Post-traumatic osteoarthritis;
- Rheumatoid arthritis.

The CTA Resurfacing Heads are indicated for partial shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:

- Rotator cuff tear arthropathy.

The humeral heads and stems are intended for uncemented use only. The glenoid components, used in total shoulder replacement, are intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112900